

June 13, 2005

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

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## **CITIZEN PETITION**

The undersigned submits this petition under Section 21 C.F.R. § 314.93, § 10.20, and § 10.30 to request permission from the Commissioner of Food and Drugs to market and sale of a proposed drug product that differs from the non-reference listed drug in one inactive ingredient.

### **A. Action Requested**

We request the Food and Drug Administration (FDA) permit marketing and sale of 2% lidocaine hydrochloride for topical (spray) anesthesia with a flavor as an inactive ingredient, whereas, a flavor is selected from the list of FDA-approved inactive ingredients.

### **B. Statement of Grounds**

#### **1. Rationale for Proposed Product**

The non-referenced listed drug LIDOCAINE HCL (Lidocaine Hydrochloride). Among other forms, LIDOCAINE HCL is available in a 2% solution, listed in the 2005 Orange Book as "LIDOCAINE HCL" sponsored by POLYMEDICA under the name ANESTACON. This petition request permission to market and sale of product containing a 2% solution of non-referenced listed drug LIDOCAINE HCL and a flavor, an additional inactive ingredient selected from the list of FDA-approved inactive ingredients. Topical lidocaine is ubiquitous in an otolaryngology practice. Used in small doses (less than 1cc), as a spray in the nose, it helps to facilitate nasal and laryngeal endoscopy; when applied topically in the mouth. It is used prior to local infiltration anesthesia and in combination with other medications as a gargle to help relieve post-operative pain. Yet though safe and effective, the taste of this

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medication is universally disliked by all patients. The proposed product would be the first lidocaine product providing a safe application of an excellent anesthetic and a pleasant taste for a patient. The proposed product when used topically in the nasal and oral cavities overcomes the patients' objection to unpleasant taste of the current product and facilitates the doctor-patient relationship in a case of taste-sensitive patients such as children.

The proposed product for a example will contain a flavor out of the following flavors selected from the list of FDA-approved inactive ingredients: FLAVOR CHERRY 1566, FLAVOR GRAPE 501040A, FLAVOR ORANGE #7679, FLAVOR PEACH 302789, FLAVOR PEACH 302789, FLAVOR PEPPERMINT STICK FMC 16170, FLAVOR RASPBERRY 65934, FLAVOR STRAWBERRY 14953, FLAVOR TROPICAL FRUIT PUNCH 1591, FLAVOR WILD CHERRY 29653, FLAVOR APRICOT 24829, FLAVOR BERRY CITRUS BLEND 9621. All flavors will be used in concentration not exceeding the FDA approved concentration for the corresponding flavor.

## **2. Prior Related Submissions.**

None.

### **C. Environmental Impact**

This petition is eligible for a categorical exclusion under 21 C.F.R. § 25.31(a) because approval of this petition will not increase the use of the active ingredient. The proposed product will not be administered at higher dosage levels, for longer duration, or for different indications than the listed drug.

### **D. Economic Impact**

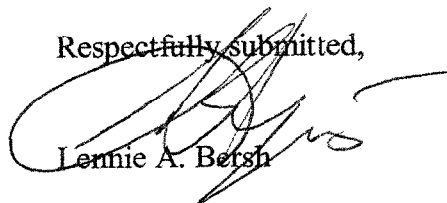
Information on economic impact will be submitted upon request.

### **E. Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it

includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Lennie A. Bersh', is written over the typed name.

Lennie A. Bersh  
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